

VPI96-14 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : David M. Naff  
Group : 1651  
Applicants : Alexey L. Margolin et al.  
Application No.: 09/631,241 Confirmation No.:9677  
Filed : August 2, 2000  
For : CONTROLLED DISSOLUTION CROSSLINKED  
PROTEIN CRYSTALS

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TECH CENTER 1600/2900

New York, New York  
March 27, 2001

Hon. Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted more than three months from the application filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of either a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311.

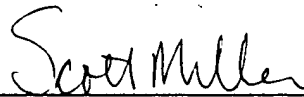
In accordance with 37 C.F.R. § 1.97, this Statement is accompanied by:

[ ] a certification as required under 37 C.F.R.  
§ 1.97(e)(1) or § 1.97(e)(2);

[x] the fee as set forth in 37 C.F.R. § 1.17(p).

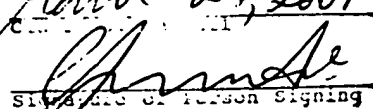
The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the accompanying Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

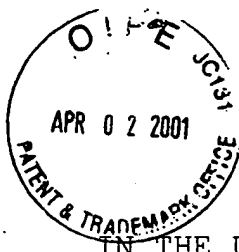
Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)  
Margaret A. Pierri (Reg. No. 30,709)  
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STATEMENT UNDER 37 C.F.R. § 1.56 AND § 1.97(c)

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants,  
through their attorneys, make of record the following documents:

United States Patents

4,373,023 - "Process For Neutralizing Heparin," to  
Robert S. Langer, et al, issued February 8, 1983.

4,579,779 - "Method of encapsulating volatile organic  
liquids," to S. Ohno, issued April 1, 1986.

4,606,909 - "Pharmaceutical multiple-units  
formulation," H. Bechgaard et al., issued August 19, 1986.

4,760,025 - "Modified enzymes and methods for making  
same," to D.A. Estell et al., issued July 26, 1988.

5,066,490 - "Protein crosslinking reagents cleavable within acidified intracellular vesicles" to D.M. Neville, Jr. et al., issued November 19, 1991.

5,120,650 - "Method for producing crystalline glucose isomerase," to K. Visuri, issued June 9, 1992.

5,286,404 - "Liquid enzymatic detergent composition," to N. Eriksen et al., issued February 15, 1994.

5,385,959 - "Capsule which comprises a component subject to degradation and a composite polymer," to L.S. Tsaur et al., issued January 31, 1995.

5,500,223 - "Encapsulating method and products containing encapsulated material," to J.M. Behan et al., issued March 19, 1996.

5,508,164 - "Isolation of biological materials using magnetic particles", to A.P. Kausch et al., issued April 16, 1996.

5,569,467 - "Process for the preparation of microballs and microballs thus obtained," to J.M. Ruiz, issued October 29, 1996.

5,593,697 - "Single dose vaccination system," to I.G. Barr et al., issued January 14, 1997.

5,603,956 - "Cross-linked enzymatically controlled drug release," to M.A. Mateescu et al., issued February 18, 1997.

5,618,710 - "Crosslinked enzyme crystals", to M.A. Navia et al., issued April 8, 1997.

6,140,475 - "Controlled Dissolution Crosslinked Protein Crystals", to A.L. Margolin et al., issued October 31, 2000.

#### PCT Patent Applications

WO 89/06279, published July 13, 1989.

WO 98/13119, published April 2, 1998.

WO 92/02617, published February 20, 1992.

WO 97/44445, published November 27, 1997.

### European Patent Applications

O 341 503, published November 15, 1989.

### Japanese Patent Application Abstract

Derwent Abstract XP-002066465, JP860159799, published 1988.

### Other Documents

A. Dyer et al., "A thermal investigation of the stability of crystalline cross-linked carboxypeptidase A", Thermochimica Acta, vol. 8, pps. 455-464 (1974).

David J. Haas, "Preliminary studies on the denaturation of cross-linked lysozyme crystals", Biophysical Journal, vol. 8, pps. 549-555 (1968).

Peter J. Kasvinsky et al., "Activity of glycogen phosphorylase in the crystalline state", The Journal of Biological Chemistry, vol. 251, No. 21, pps. 6852-6859 (1976).

Jim J. Lalonde et al., "Cross-linked crystals of candida rugosa lipase: highly efficient catalysts for the resolution of chiral esters", Journal of the American Chemical Society, vol. 117, pps. 6845-6852 (1995).

Kang Min Lee et al., "Crosslinked crystalline horse liver alcohol dehydrogenase as a redox catalyst: activity and stability toward organic solvent", Bioorganic Chemistry, vol. 14, pps. 202-210 (1986).

Alexey L. Margolin, "Novel crystalline catalysts," TIBTECH vol. 14, pps. 223-230 (1996).

Nancy L. St. Clair et al., "Cross-linked enzyme crystals as robust biocatalysts", Journal of the American Chemical Society, vol. 114, pps. 7314-7316 (1992).

Eric Tuchsén et al., "Kinetic properties of subtilisin type carlsberg in the crystalline state," Carlsberg Research Communications, vol. 42, pps. 407-420 (1977).

Kui Xu et al., "pH Control of the catalytic activity of cross-linked enzyme crystals in organic solvents", Journal of the American Chemical Society, vol. 118, pps. 9815-9819 (1996).

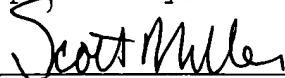
A. Yonath et al., "Crystallographic studies of protein denaturation and renaturation", Biochemistry, vol. 16, No. 7, pps. 1413-1417 (1977).

V.P. Torchilin et al., "Principles of enzyme stabilization. V. Possibility of enzyme selfstabilization under the action of potentially reversible intramolecular cross-linkages of different length", Biochimica et Biophysica Acta, vol. 658, pps. 1-10 (1979).

Fluka Catalogue, "Reagents for protein modification", Chapter Crosslinkers, 61-67 (1986).

Applicants have attached a PTO-1449 Form listing these documents. The above-cited documents, made of record by applicants, do not render the claims of this application unpatentable. Applicants request that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. As applicants are submitting this statement after the issuance of a first Office Action on the merits, applicants have enclosed a check for \$180.00 in payment of the required fee [37 C.F.R. §§ 1.98 and 1.17(p)].

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)

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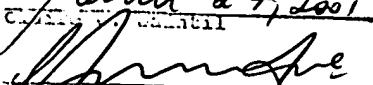
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